

September 18, 2019

VIA EMAIL TO: wmelofchik@ncoil.org

The Honorable Maggie Carlton, Chair
The Honorable David Santiago, Vice Chair
National Council of Insurance Legislators
Workers' Compensation Insurance Committee
National Council of Insurance Legislators
2317 Route 34, Suite 2B
Manasquan, NJ 08736

Dear Assemblywoman Carlton and Representative Santiago:

On behalf of Medtronic, I am writing to respectfully request an amendment to the current draft of the "Model Workers' Compensation Drug Formulary Act" to clarify that a formulary adopted would not apply to intrathecal medications delivered by an implanted pump.

Medtronic is a global medical technology, services and solutions company with a variety of therapies to serve our patients. This includes an implantable drug delivery system (IDDS) for the treatment of chronic, intractable pain. An IDDS is an implanted pump and catheter, programmed by a physician, that releases prescribed amounts of pain medication directly into the intrathecal space, near pain receptors in the spine instead of the circulatory system (at a fraction of the oral medication dose and with fewer side effects than associated with oral medication).¹

As you know, we are facing an unprecedented opioid crisis and it is important to emphasize the interrelation between that crisis and pain management. An estimated 11.4 million Americans are misusing opioids with 63% doing so to relieve physical pain² and an estimated 25% of chronic pain patients are misusing prescription oral opioids.³ That is why it is critical to preserve options for physicians using alternatives to oral opioids such as IDDS. In fact, the Food and Drug Administration's updated opioid education Blueprint includes the use of approved/cleared medical devices for pain management.⁴

As further background, clinical evidence has shown a reduction in the use of oral opioids in managing and treating chronic pain with IDDS. A retrospective claims analysis found that 51% of chronic non-cancer pain patients eliminated oral opioids within one year of IDDS therapy. This elimination resulted in a 10% to 17% reduction in yearly inpatient, outpatient, and drug expenditures.⁵ Finally, Medtronic's Control WorkflowSM approach is designed to help physicians and patients eliminate oral opioids while utilizing low-dose intrathecal therapy for pain relief through this therapy.

For these reasons and to avoid confusion for physicians that utilize IDDS, many of whom are working to wean patients off oral opioids, we respectfully suggest clarifying Section 3 using the following red-lined language:

Section 3. Selection of Drug Formulary

(A) It is the intent of the Legislature that the [insert appropriate state agency/department] select a nationally recognized, evidence-based drug formulary, for use in the workers' compensation system. Such formulary shall apply to prescription drugs that are prescribed and dispensed for outpatient use in connection with workers' compensation claims with a date of injury on or after [insert date]. The drug formulary shall not apply to intrathecal drugs delivered by an implanted pump or to care provided in an emergency department or inpatient setting.

Thank you for your consideration and enclosed you will find a recent Medtronic white paper related to the opioid epidemic for further discussion of this issue. If you have questions, please do not hesitate to contact me using the information below.

Sincerely,

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Enclosure

¹ Hamza M, Doleys D, Wells M, et al. Prospective study of 3-year follow-up of low dose intrathecal opioids in the management of chronic nonmalignant pain. *Pain Med.* 2012;13: 1304-1313.

² Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: results from the 2016 national survey on drug use and health. HHS publication no. SMA 17-5044, NSDUH Series H-52. 2017; Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration; <https://www.samhsa.gov/data/sites/default/files/NSDUH-FFR1-2016/NSDUH-FFR1-2016.htm>. Accessed July 2018.

³ Vowles KE, McEntee ML, Julnes PS, et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. *Pain.* 2015;156(4):569-576.

⁴ US Food and Drug Administration. FDA's opioid analgesic REMS education blueprint for health care providers involved in the treatment and monitoring of patients with pain, September 2018. https://www.accessdata.fda.gov/drugsatfda_docs/rems/Opioid_analgesic_2018_09_18_FDA_Blueprint.pdf, Accessed May 2019.

⁵ Hatheway JA, Caraway D, David G, et al. Systemic opioid elimination after implantation of an intrathecal drug delivery system significantly reduced health-care expenditures. *Neuromodulation: journal of the International Neuromodulation Society.* 2015;18(3):207-213.